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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,079	11/02/2005	Vernon L. Alvarez	2006636-0026	2000
24280 7590 06/11/2009 CHOATE, HALL & STEWART LLP TWO INTERNATIONAL PLACE BOSTON, MA 02110				
EXAMINER NIEBAUER, RONALD T				
ART UNIT		PAPER NUMBER		
1654				
NOTIFICATION DATE		DELIVERY MODE		
06/11/2009		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@choate.com

### Office Action Summary

**Application No.**

10/516,079

**Applicant(s)**

ALVAREZ ET AL.

**Examiner**

RONALD T. NIEBAUER

**Art Unit**

1654

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6, 9-12 and 18-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 9-12 and 18-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S5108)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(c), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(c) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/27/09 has been entered.

Applicants amendments and arguments filed 2/27/09 are acknowledged and have been fully considered. Claims 1 and 9 have been amended. Any rejection and/or objection not specifically addressed is herein withdrawn.

Applicant's previously elected SEQ ID NO:1 (native chlorotoxin, compare page 10 line 18 of the specification) as the chlorotoxin derivative and temozolomide as the chemotherapeutic agent in the reply filed on 10/17/07. In the instant case, the elected species were found in the prior art and the claims were found to be unpatentable (via 35 USC 103) over the prior art. In the course of searching for the species, any other prior art that was uncovered that reads on other species is cited herein. In accord with section 803.02 of the MPEP the claims have been examined fully with respect to the elected species.

Claims 7-8,13-17 have been cancelled.

Claims 1-6,9-12,18-21 are under consideration.

***Priority***

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(e) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed applications, Application No. 60/384,171 and Application No. 60/406,033 fail to provide adequate written description in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application.

In the instant case, claims 1,9 and dependent claims refer to SEQ ID NO:13 which as shown in the sequence listing and the last paragraph of page 11 is a generic sequence that includes X groups.

***Lack of Ipsis Verbis Support***

Application No. 60/384,171 and Application No. 60/406,033 are void of support for SEQ ID NO:13.

***Lack of Implicit or Inherent Support***

Section 2163 of the MPEP states: 'While there is no in haec verba requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure'.

Although the above statement is with respect to new claim limitations, the analysis is similar in determining conditions for receiving the benefit of an earlier filing date.

Application No. 60/384,171 recites SEQ ID NO: 1-7. However, each of SEQ ID NO:1-7 are specific amino acid sequences that do not include any X groups. From the disclosure of Application No. 60/384,171 there is nothing to lead one to SEQ ID NO:13. As such, one would not conclude that Application No. 60/384,171 provides adequate support for the instant claims.

Application No. 60/406,033 recites SEQ ID NO: 1-7. However, each of SEQ ID NO:1-7 are specific amino acid sequences that do not include any X groups. From the disclosure of Application No. 60/406,033 there is nothing to lead one to SEQ ID NO:13. As such, one would not conclude that Application No. 60/406,033 provides adequate support for the instant claims.

It is noted that section 706.02 VI D of the MPEP sets forth the method to determine the effective filing date. In particular, 'If the application properly claims benefit under 35 U.S.C. 119(e) to a provisional application, the effective filing date is the filing date of the provisional application for any claims which are fully supported under the first paragraph of 35 U.S.C. 112 by the provisional application.'. In the instant case, none of the claims are fully supported by the provisional Application No. 60/384,171 or Application No. 60/406,033. As such, none of the claims receive the benefit of the provisional application. It is noted that claims are either fully supported or not fully supported. In other words, claims are not treated as 'supported in part' even though one particular element may be supported in the provisional

application. As such, for purposes of searching for prior art, a priority date of 6/2/03 is used for the instant claims.

### ***Claim Objections***

Claims 1,6,11,12 are objected to because of the following informalities:

Claims 1 and 12 refer to 'glioblastomamultiforme'. Applicants specification (page 1 lines 25-26) and the art recognize that this phrase is usually 2 separate words (i.e. glioblastoma multiforme).

Claims 6 and 11 refer to BCNU. The meaning of the abbreviation should be spelled out the first time it is used in the claims.

Appropriate correction is required.

### ***Specification***

The disclosure is objected to because of the following informalities:

37 CFR 1.821(d) states:

"Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO: " in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application."

In the instant case, Figures 10,13-14 refer to numerous sequences which appear to be included in the 95 sequences submitted with the application. However, the sequences do not include sequence identifiers.

Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

Claims were rejected under 103 using the references cited below in the previous office action. Since the claims have been amended, the rejection has been updated.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 1-6,9-12,18-21** are rejected under 35 U.S.C. 103(a) as being unpatentable over Samoylova et al. (US 2003/0216322 as cited previously) and Stupp et al. (The Lancet v2 Sept 2001 552-560 as cited previously).

Samoylova teach peptides for recognition and targeting of glial cell tumors (title) and compositions comprising peptides for therapy of cancer cells (abstract). Samoylova teach that the peptides of the invention are broadly defined to be peptides that bind glioma cells (section 0032 for example). Samoylova teach that the peptides may be used to target chemotherapeutic agents to treat gliomas (sections 0065-0066). Samoylova teach a need for therapies for brain tumor patients (section 0008) and specifically teach patient populations with glioblastomas (section 0004). Samoylova teach specific compositions comprising a peptide and a chemotherapeutic agent (claim 4, section 0068). Samoylova teach the administration of a peptide conjugated to methotrexate (a chemotherapeutic agent specifically an anti-metabolite) in example 3 (section 0132). In addition to simultaneous administration via a conjugate, Samoylova teach compositions in which the peptide and chemotherapeutic agent are not conjugated to one another (section 0068). Samoylova teach compositions with a pharmaceutically acceptable carrier (section 0069).

Samoylova et al. does not expressly recite an embodiment with chlorotoxin as the peptide (instead Samoylova teach phage derived peptides). Samoylova does not expressly teach the chemotherapeutic agent temozolomide.

Samoylova does teach chlorotoxin (section 0010) (equivalent to SEQ ID NO:1 of the current invention, the elected species of chlorotoxin) as a peptide that specifically binds to



glioma cells and that the chlorotoxin peptide shows high-affinity specific binding to gliomas and may find use in therapeutic applications. Since Samoylova teach that the peptides of the invention are broadly defined to be peptides that bind glioma cells (section 0032 for example) one would recognize that the peptides are not limited to the peptides recited in the examples or claims. Since Samoylova teach chlorotoxin as a peptide that specifically binds to glioma cells and that the chlorotoxin peptide shows high-affinity specific binding to gliomas (section 0010) one would be motivated to use the chlorotoxin as the peptide of the instant invention. Further it is noted that Samoylova acknowledge that an array of markers will be necessary for targeting gliomas so one would be motivated to use various peptides (section 0013).

Since Samoylova teach a need for therapies for brain tumor patients (section 0008) and specifically teach patient populations with glioblastomas (section 0004) one would be motivated to treat those with glioblastomas (also known as glioblastoma multiforme). Since Samoylova teach that the peptides may be used to target chemotherapeutic agents to treat gliomas (section 0065) and specifically teach administration of a peptide conjugated to methotrexate (a chemotherapeutic agent specifically an anti-metabolite) in example 3 one would be motivated to incorporate an appropriate agent to target glioblastomas.

Stupp teach the administration of the alkylating agent/chemotherapeutic agent temozolomide (abstract). Stupp specifically teach temozolomide for brain tumours and glioma (abstract). Stupp teach temozolomide with other active agents against brain tumours (abstract and page 557-558). Stupp specifically teach that temozolomide can be used sequentially with other agents (page 557 1<sup>st</sup> column last paragraph) and also in a variety of combination dosing

schedules (page 557-558), and in combination with more than one agent (page 558 first column last paragraph).

One would have been motivated to combine the chemotherapeutic agent temozolomide as taught by Stupp into the method/compositions of Samoylova since both references deal with therapeutics specifically of brain tumors. Both references motivate the use of combination therapies.

Taken together one would be motivated to administer a composition comprising chlorotoxin which reads on SEQ ID NO:1 of the instant invention and temozolomide which is an alkylating agent combined as a conjugate to those with glioblastomas (also known as glioblastoma multiforme) thus meeting the limitations of claims 1,4-6,9-12,18,20 of the instant invention. It is noted that claim 9 recites 'for treating cancer' and claim 12 recites 'wherein the cancer is ...'. Such recitations do not result in a structural difference and do not limit the instant claims, thus the references obviate the instant claims. In addition to simultaneous administration via a conjugate, Samoylova teach compositions in which the peptide and chemotherapeutic agent are not conjugated to one another (section 0068) thus meeting the limitations of claims 2-3 of the instant invention. Samoylova teach compositions with a pharmaceutically acceptable carrier (section 0069) as recited in claim 19. Since Stupp specifically teach that temozolomide can be used sequentially with other agents (page 557 1<sup>st</sup> column last paragraph) and also in a variety of combination dosing schedules (page 557-558), and in combination with more than one agent (page 558 first column last paragraph) one would be motivated to conjugate the chlorotoxin to multiple chemotherapeutic agents as recited in claim 21.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Further, it is noted that it is obvious to combine known elements to be used for the same purpose and that the motivation to combine them flows logically from their being taught in the prior art (MPEP 2144.06). In the instant case, both chlorotoxin and temozolomide were each individually taught in methods and compositions for treating brain tumors.

#### ***Response to Arguments 103 rejection***

Since the claims have been amended, a new rejection adapted to the claims is recited above using the same references as in the previous rejection. Applicants arguments will be considered to the extent that they apply to the current rejection and claim set.

Applicants argue that Samoylova teaches away from the claimed invention. Applicants argue that Samoylova disparages chlorotoxin in section 0012.

Applicants argue that Samoylova provides no motivation to combine chlorotoxin with a chemotherapeutic agent or at best provides motivation to combine different peptides.

Applicant's arguments filed 2/27/09 have been fully considered but they are not persuasive.

Although Applicants argue that Samoylova teaches away from the claimed invention, section 2123 of the MPEP states that references may be relied upon for all that they suggest include nonpreferred embodiments. In the instant case, Samoylova expressly teach that the

chlorotoxin peptide shows high-affinity specific binding to glioma cells and may find use in therapeutic applications (section 0010). Although applicants argue that section 0012 of Samoylova is disparaging, section 0012 simply suggests that no single marker will be able to target all gliomas and that an array of markers will be necessary. Since an array (i.e. more than one) of markers will be needed one would not be limited to a single marker and would be motivated to use various markers such as chlorotoxin. Further, it is noted that section 0012 refers to diagnosis while section 0010 refers to therapies which are not necessarily the same.

Although Applicants argue that Samoylova provides no motivation to combine chlorotoxin with a chemotherapeutic agent, Samoylova teach that the peptides of the invention are broadly defined to be peptides that bind glioma cells (section 0032 for example) and one would recognize that the peptides are not limited to the peptides recited in the examples or claims. Since Samoylova teach chlorotoxin as a peptide that specifically binds to glioma cells and that the chlorotoxin peptide shows high-affinity specific binding to gliomas (section 0010) one would be motivated to use the chlorotoxin as the peptide of the instant invention. Since Samoylova teach that the peptides may be used to target chemotherapeutic agents to treat gliomas (section 0065) and specifically teach administration of a peptide conjugated to methotrexate (a chemotherapeutic agent specifically an anti-metabolite) in example 3 one would be motivated to incorporate an appropriate agent to target glioblastomas. Samoylova teach specific compositions comprising a peptide and a chemotherapeutic agent (claim 4, section 0068). Samoylova teach peptides for recognition and targeting of glial cell tumors (title) and compositions for use in therapy of cancer cells (abstract). Samoylova teach a need for therapies for brain tumor patients (section 0008) and specifically teach patient populations with

glioblastomas (section 0004). As such, the recognized problem is effective therapy of gliomas, specifically using peptides that bind to gliomas with high specificity (section 0032). Samoylova teach peptides that bind to glioma cells that were identified using a phage display library (section 0037-0038, claim 10). Samoylova teach that the peptides were isolated for the ability to bind glioma cells (section 0037). Samoylova teach (section 0010) that the peptide chlorotoxin shows high-affinity, specific binding to glioma cells. Samoylova even goes so far as to provide a further suggestion that the chlorotoxin peptide may find use in therapeutic applications (section 0010). As such, there is an express suggestion within the reference to modify the reference contrary to applicants assertion that there is no direction toward the use of chlorotoxin peptides. Further, a disclosure of alternate peptides with specific functions does not discredit one peptide over the other. Taken together, Samoylova teach peptides such as the peptide of claim 10 that binds to gliomas with high specificity. Further, Samoylova teach that the peptide chlorotoxin shows high-affinity, specific binding to glioma cells (section 0010). Therefore the peptide of claim 10 and the chlorotoxin peptide were known in the art as well as their ability to bind to gliomas with high specificity.

### ***Double Patenting***

Claims were rejected based on the applications and references cited below in the previous office action. Since the claims have been amended, the rejection has been updated.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined

application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

**Claims 1-6,18-21** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 42-49 of copending Application No. 10/522,810 ('810) in view of Stupp et al. (The Lancet v2 Sept 2001 552-560) and Samoylova et al. (US 2003/0216322 as cited previously).

'810 teach administration of SEQ ID NO:13 (the same SEQ ID NO:13 as in the instant invention) to prostate cancer cells and gliomas (claims 42,47) thus meeting the patient population and chlorotoxin derivative limitations as recited in the instant claims. '810 teach a composition conjugated to a cytotoxic agent for binding to cancer cells (claim 48).

'810 does not teach the specific cytotoxic agent of the current invention.

Stupp specifically teach temozolomide compositions for brain tumours and glioma (abstract). Stupp teach temozolomide with other active agents against brain tumors (abstract and page 557-558). Stupp teach that temozolomide is a cytotoxic agent (page 553 2<sup>nd</sup> full paragraph line 13). Since '810 teach gliomas one would be motivated to use agents against gliomas such as temozolomide as taught by Stupp. Since '810 teach linking the agent (claim 48) the limitations of

claims 1,4-6,9-12,18,20 are met. Further, as discussed above, Samoylova teach compositions in which the peptide and chemotherapeutic agent are not conjugated to one another (section 0068) thus meeting the limitations of claims 2-3 of the instant invention. . Samoylova teach compositions with a pharmaceutically acceptable carrier (section 0069) as recited in claim 19. Since Stupp specifically teach that temozolamide can be used sequentially with other agents (page 557 1<sup>st</sup> column last paragraph) and also in a variety of combination dosing schedules (page 557-558), and in combination with more than one agent (page 558 first column last paragraph) one would be motivated to conjugate the chlorotoxin to multiple chemotherapeutic agents as recited in claim 21.

This is a provisional obviousness-type double patenting rejection.

**Claims 1-6,9-12,18-21** remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4,11,30-48 of copending Application No. 11/731,661 ('661) in view of Samoylova et al. (US 2003/0216322) and Stupp et al. (The Lancet v2 Sept 2001 552-560).

'661 teach a method of administering a chlorotoxin conjugate (claim 4) and a chemotherapeutic agent (claim 23) to patients with lung carcinoma.

As discussed above, Samoylova and Stupp teach the remaining claim limitations. In the instant case, all the claimed elements were taught in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

This is a provisional obviousness-type double patenting rejection.

**Claims 1-6,9-12,18-21** remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4,21 of copending Application No. 11/547,875 ('875) in view of Stupp et al. (The Lancet v2 Sept 2001 552-560) and Samoylova et al. (US 2003/0216322).

'875 teach administration of a composition comprising chlorotoxin (claim 4) and a cytotoxic agent (claim 35,43,44) to patients with cancer.

As discussed above, Samoylova and Stupp teach the remaining claim limitations. In the instant case, all the claimed elements were taught in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

This is a provisional obviousness-type double patenting rejection.

The claims as specified above are directed to an invention not patentably distinct from the claims specified above of commonly assigned 10/522,810; 11/731,661; 11/547,875. Specifically, see above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 10/522,810; 11/731,661; 11/547,875, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case



qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

***Response to Arguments Double Patenting***

Since the claims have been amended, a new rejection adapted to the claims is recited above using the same reference applications and references as in the previous rejection. Applicants arguments will be considered to the extent that they apply to the current rejection and claim set.

Applicants request that the rejections be held in abeyance.

Applicant's arguments filed 2/27/09 have been fully considered but they are not persuasive.

Although Applicants request that the rejections be held in abeyance, the outstanding double patenting rejections have not been overcome. As such, the claims are rejected.

***Prior Art of Record***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Deshane et al (JBC v278 2002 page 4135-4144 as cited in IDS 10/11/07 cite 5 of npl section). It is noted that Deshane was published on-line in November 25,2002. As discussed in the priority section, a priority date of 6/2/03 is used for the instant claims. Deshane teach that chlorotoxin inhibits glioma cell invasion (title) and that chlorotoxin has significant therapeutic potential for gliomas (abstract).

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD T. NIEBAUER whose telephone number is (571)270-3059. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, alt. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ronald T Niebauer/  
Examiner, Art Unit 1654

/Cecilia Tsang/  
Supervisory Patent Examiner, Art Unit 1654